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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,152	08/04/2006	James Peter Burnie	87278.2760	8989

30734 7590 12/03/2009  
BAKER & HOSTETLER LLP  
WASHINGTON SQUARE, SUITE 1100  
1050 CONNECTICUT AVE. N.W.  
WASHINGTON, DC 20036-5304

EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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12/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@bakerlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,152	<b>Applicant(s)</b> BURNIE ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43 is/are allowed.
- 6) ☒ Claim(s) 19-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 1 September 2009, is acknowledged.

Claims 22, 31, 41, 42 and 43 have been amended.

2. Claims 19-43 are pending and under consideration.

### **Rejections Withdrawn**

3. The objection to claim 41 is withdrawn in light of the amendment of the claim.

4. The provisional rejection of claims 19, 20, 21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 15 of copending Application No. 11/630,926 is withdrawn in light of the allowance of application no. 11/630,926 which necessitates the change from provisional rejection to new rejection, see following.

5. The rejection of claims 41-43 under 35 U.S.C. 112, second paragraph, as being indefinite for antibodies "specific against at least one antigen", is withdrawn in light of the amendment of the claims to recite that the antibody binds specifically to the antigen produced by *C. difficile*.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 19, 20 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 7,608,265, issued on 27 October 2009. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to antibody or antigen binding fragments thereof "having" SEQ ID NO:27 or SEQ ID NO:32 (instant claims) or "having" SEQ ID NO:1 or 41 (11/630,926). The open language in the recitation of the antibody/fragment "having" a particular sequence is deemed open language, i.e., comprising. Both SEQ ID NO:1 and 41 "comprise" SEQ ID NO:27.

Applicants request deferral of the issue until there is allowable matter.

### **Rejections Maintained**

7. The rejection of claims 22-36 under 35 U.S.C. 112, second paragraph, as being indefinite for antibodies "specific against at least one antigen", is maintained.

Applicants argue that the claims have been amended to include subject indicated as allowable and are therefore also in condition for allowance.

The examiner has considered applicants' argument, in light of the claim amendments, but does not find it persuasive.

As newly amended, claim 22, step (iii) recites "confirming that an antibody comprising the dominant sequence is therapeutically effective against *Clostridium difficile*". This does not rectify the indefiniteness for antibody specificity. The claim is drawn to a method for identifying candidate **antigen-specific sequences** of antibodies specific against **at least one antigen**

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**produced by *Clostridium difficile*.** Step (i) remains drawn to obtaining all B cells from  $\geq 1$  patient exposed to the antigen and sequencing any CDR3 region of VH or VL. Step (ii) remains drawn to detecting a set of sequences that occur in total at a frequency of  $\geq 1\%$ . Step (iii) as amended does not require that the products of steps (i) and (ii) are specific against at least one antigen produced by *C. difficile*, only that the antibody comprising the dominant sequence is therapeutically effective against *C. difficile*. Thus, there is no requirement that the antibody have the specificity that the method claims.

Claims 23-36 depend from claim 22, but do not clarify the issue.

8. The rejection of claims 37-39 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is maintained for reasons of record.

### **Conclusion**

9. Claims 19-39 are finally rejected.

10. The conversion of co-pending application 11/630,926 to Patent No. 7,608,265 necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 2, 2009